

FORM PTO-1449
U.S. Department of Commerce Patent and
Trademark Office

Docket No. STEM1110

Serial No.: 09/641,587

Applicant(s): Twardzik, et al.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Filing Date: August 18, 2000

Group Art Unit: 1633

U.S. PTO
1050 39 118
01/04/02

U.S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
<i>SD</i>		5,690,928	11/25/97	Heimbrook et al.			

FOREIGN PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
<i>SD</i>		WO 95/24466	14.09.95	PCT		/	
<i>II</i>		WO 97/25349	17.07.97	PCT		/	
<i>V</i>		WO 96/21676	18.07.96	PCT		/	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

EXAMINER <i>Stephen Guckler</i>	DATE CONSIDERED <i>5/17/04</i>
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Docket No.
STEM1110-2

Serial No.:
09/641,587



Applicant(s): Twardzik, et al.

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Filing Date:
August 17, 2000

Group Art Unit:
Unassigned

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<i>St</i>	AA	Nestor et al., "A Synthetic Fragment of Rat Transforming Growth Factor α With Receptor Binding and Antigenic Properties," <i>Biochemical and Biophysical Research Communications</i> 129(1):226-232 (1985).
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Form PTO-1449
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Docket No.
STEM1110-4

Serial No.:
10/039,119

Applicants: Twardzik et al.

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT BY APPLICANT

Filing Date:
January 4, 2002

Group Art Unit:
1647

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U.S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
SD	AA	4,742,003	05/03/1988	Derynck and Goeddel			
II	AB	4,749,683	06/07/1988	Murphy and Rhodes			
II	AC	4,863,899	09/05/1989	George J. Todaro			
II	AD	4,863,902	09/05/1989	Amagase et al			
II	AE	4,874,746	10/17/1989	Antoniades and Lynch			
II	AF	5,102,870	04/7/1992	Florine and Smith			
II	AG	5,229,493	07/20/1993	Folkman et al.			
II	AH	5,328,986	07/12/1994	Folkman and Shing			
II	AI	5,750,376	05/12/1998	Weiss et al.			
II	AJ	5,814,308	09/29/1998	Ke Zhang			
II	AK	5,851,832	12/22/1998	Weiss et al.			
II	AL	5,885,956	03/23/1999	Nardi and Brand			
II	AM	5,886,141	03/23/1999	Folkman et al.			
II	AN	5,902,799	05/11/1999	Herrmann et al.			
II	AO	5,980,885	11/09/1999	Weiss and Reynolds			
II	AP	5,981,165	11/09/1999	Weiss and Reynolds			

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Stephen Suckler

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Filing Date: Janauary 4, 2002	Group Art Unit: 1647

<i>S6</i>	AQ	6,011,004	01/04/2000	Kessler and Apfel				
<i>11</i>	AR	6,013,762	01/11/2000	Folkman et al.				
<i>11</i>	AS	6,071,889	06/06/2000	Weiss et al.				
<i>11</i>	AT	6,114,307	09/05/2000	Jaspers et al.				
<i>11</i>	AU	6,232,288 BI	05/15/2001	Itaru Kojima				
<i>11</i>	AV	6,288,301 BI	09/11/2001	Nardi and Brand				
<i>11</i>	AW	6,326,201 BI	12/04/2001	Fung et al.				

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<i>S6</i>	AX	WO 84/01106	03/29/1984	PCT			
<i>11</i>	AY	0 154 434 A1	09/11/1985	EP			
<i>11</i>	AZ	WO 94/16718	08/04/1994	PCT			
<i>11</i>	BA	WO 98/22127	05/28/1998	PCT			
<i>11</i>	BB	WO 99/06060	02/11/1999	PCT			
<i>11</i>	BC	WO 00/44400	08/03/2000	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

<i>S6</i>	BD	Blikslager, Anthony T. et al., "Glutamine and Transforming Growth Factor- α Stimulate Extracellular Regulated Kinases and Enhance Recovery of Villous Surface Area In Porcine Ischemic-Injured Intestine," <i>Surgery</i> , Vol. 125, No. 2, February 1999, pgs. 186-194.
<i>11</i>	BE	Blikslager, A.T. et al., "Glutamine and Transforming Growth Factor Alpha Enhance Repair of Intestinal Ischemia/Reperfusion Injury," <i>Supplement to Gastroenterology</i> , Vol. 110, No. 4, April 1996, Abstract pg. A313.

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S6	BF	Brand, Stephan A. et al., "Prolonged Efficacy of Islet Neogenesis Therapy with Gastrin and TGF α In Mature Rats with Preexisting Diabetes," <i>Diabetes</i> , Vol. 50 (Supplement), 2001, pg. A338.5630.
11	BG	Burgel, Pierre-Regis et al., "Human Eosinophils Induce Mucin Production In Airway Epithelial Cells Via Epidermal Growth Factor Receptor Activation," <i>The Journal of Immunology</i> , 2001, pgs. 5948-5954.
11	BH	Carpenter, Graham et al., "Antibodies to the Epidermal Growth Factor Receptor Block the Biological Activities of Sarcoma Growth Factor," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 80, September 1983, pgs. 5627.
11	BI	Chamberlin, Stephen G. et al., "Constrained Peptide Analogues of Transforming Growth Factor- α Residues Cysteine 21-32 Are Mitogenically Active," <i>The Journal of Biological Chemistry</i> , Vol. 270, No. 36, September 8, 1995, pgs. 21062-21067.
11	BJ	Chosidow, O. et al., "Tripe Palms Associated With Systemic Mastocytosis: The Role of Transforming Growth Factor- α and Efficacy of Interferon-Alfa," <i>British Journal of Dermatology</i> , Vol. 138, 1998, pgs. 698-703.
11	BK	Chou and Fasman, "Prediction of Protein Conformation," <i>Biochemistry</i> , Vol. 13, No. 2, 1974, pgs. 222-245.
11	BL	Coffey, Robert J. et al., "Transforming Growth Factors and Related Peptides in Gastrointestinal Neoplasia," <i>Journal of Cellular Biochemistry</i> , Supplement 16G, 1992, pgs. 111-118.
11	BM	Dayhoff, M.O. et al., "A Model of Evolutionary Change in Proteins," <i>Atlas of Protein Sequence and Structure</i> , 1972, pgs. 89-99.
11	BN	De Larco, Joseph E. et al., "Sarcoma Growth Factor from Mouse Sarcoma Virus-Transformed Cells," <i>The Journal of Biological Chemistry</i> , Vol. 255, No. 8, April 25, 1980, pgs. 3685-3690.
11	BO	Draoui, Muriel et al., "TGF α -PE40 Inhibits Non-Small Cell Lung Cancer Growth," <i>Life Sciences</i> , Vol. 54, No. 7, 1994, pgs. 445-453.
11	BP	Dunbar and Goddard, "Structure-function and Biological Role of Betacellulin," <i>The International Journal of Biochemistry & Cell Biology</i> , Vol. 32, 2000, pgs. 805-815.

EXAMINER	Stephen Twardzik	DATE CONSIDERED
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Form 1449

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56	BQ	Ebadi, M. et al., "Neurotrophins and Their Receptors In Nerve Injury and Repair," <i>Neurochem. Int.</i> , Vol. 30, Nos. 4/5, 1997, pgs. 347-374.
11	BR	Egger, B. "Reduced Susceptibility of Mice Overexpressing Transforming Growth Factor α To Dextran Sodium Sulphate Induced Colitis," <i>Gut</i> , Vol. 43, 1998, pgs. 64-70.
11	BS	Faber-Elman, A. et al., "Involvement of Wound-Associated Factors In Rat Brain Astrocyte Migratory Response to Axonal Injury In Vitro Simulation," <i>J. Clin. Invest.</i> , Vol. 97, No. 1, January 1996, pgs. 162-171.
11	BT	Ferrari, Isidre et al., "Transforming Growth Factor- α (TGF- α) and Epidermal Growth Factor-Receptor (EGF-R) Immunoreactivity In Normal and Pathologic Brain," <i>Progress In Neurobiology</i> , Vol. 49, 1996, pgs. 99-123.
11	BU	Ghielli, Manuela et al., "Regeneration Processes In the Kidney After Acute Injury: Role of Infiltrating Cells," <i>Exp. Nephrol.</i> , Vol. 6, 1998, pgs. 502-507.
11	BV	Hardie, William D. et al., "Dose-Dependent Lung Remodeling In Transgenic Mice Expressing Transforming Growth factor- α ," <i>Am. J. Physiol. Lung Cell. Mol. Physiol.</i> , Vol. 281, 2001, pgs. L1088-L1094.
11	BW	Hardie, William D. et al., "Attenuation of Acute Lung Injury In Transgenic Mice Expressing Human Transforming Growth factor- α ," <i>Am. J. Physiol.</i> , Vol. 277, 1999, pgs. L1045-L1050.
11	BX	Heidenkummer and Kampik, "Immunohistochemical Localization of Epidermal Growth Factor Receptor In A Human Epiretinal Membrane," <i>Graefes Arch. Chn. Exp. Ophthalmol.</i> , Vol. 229, 1991, pgs. 492-496.
11	BY	Ibbotson, K.J. et al., "Tumor-Derived Growth Factor Increases Bone Resorption in A Tumor Associated with Humoral Hypercalcemia of Malignancy," <i>Science</i> , Vol. 221, pgs. 1292-1294.
11	BZ	Jackowski, Andre, "Neural Injury Repair: Hope For the Future As Barriers to Effective CNS Regeneration Become Clearer," <i>British Journal of Neurosurgery</i> , Vol. 9, 1995, pgs. 303-317.

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<i>Stephen Gruel</i>	5/17/04

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S6	CA	Jackson, Bruce A. et al., "Effects of transforming Growth Factor β and Interleukin-1 β on Expression of Cyclooxygenase 1 and 2 and Phospholipase A ₂ mRNA In Lung Fibroblasts and Endothelial Cells in Culture," <i>Biochemical and Biophysical Research Communications</i> , Vol. 197, No. 3, December 30, 1993, pgs. 1465-1474.
(1)	CB	Jayaraman, Gurunathan et al., "Conformational Studies of a Synthetic Cyclic Decapeptide Fragment of Rat Transforming Growth Factor- α ," <i>Int. J. Peptide Protein Res.</i> , Vol. 46, 1995, pgs. 88-96.
(1)	CC	Jones, M.K. et al., "Gastrointestinal Mucosal Regeneration: Role of Growth Factors," <i>Frontiers in Bioscience</i> , Vol. 4, March 15, 1999, pgs. d303-309.
(1)	CD	Kheradmand, Farrah et al., "Transforming Growth Factor- α Enhances Alveolar Epithelial cell Repair In a New In Vitro Model," <i>Am. J. Physiol.</i> , Vol. 267, 1994, pgs. L728-L738.
(1)	CE	Kobayashi, Kenzo et al., "The Mechanisms of Gastrointestinal Mucosal Injury and Repair," <i>Japanese Journal of Clinica</i> , Vol. 56, No. 9, September 15, 1998, pgs. 7 (2215)-14 (2222) (English abstract).
(1)	CF	Konturek, Peter Ch. Et al., "Epidermal Growth Factor and Transforming Growth Factor- α : Role In Protection and Healing of Gastric Mucosal Lesions," <i>European Journal of Gastroenterology & Hepatology</i> , Vol. 7, 1995, pgs. 933-938.
(1)	CG	Konturek, S.J. et al., "Transforming Growth Factor Alpha and Epidermal Growth Factor In Protection and Healing of Gastric Mucosal Injury," <i>Scand. J. Gastroenterol.</i> , Vol. 27, 1992, pgs. 649-655.
(1)	CH	Kornblum, Harley I. et al., "Prenatal Ontogeny of the Epidermal Growth Factor Receptor and Its Ligand, Transforming Growth Factor Alpha, in the Rat Brain," <i>The Journal of Comparative Neurology</i> , Vol. 380, 1997, pgs. 243-261.
(1)	CI	Kudlow, Jeffrey E. et al., "Inability of Anti-Epidermal Growth Factor Receptor Monoclonal Antibody to Block "Autocrine" Growth Stimulation in Transforming Growth Factor-Secreting Melanoma Cells," <i>The Journal of Biological Chemistry</i> , Vol. 259, No. 19, October 10, 1984, pgs. 11895-11900.
(1)	CJ	Lefebvre, Ph. P. et al., "Regeneration of the Neurosensory Structures in the Mammalian Inner Ear," <i>Acta. Oto-rhino-laryngologica belg.</i> , Vol. 51, 1997, pgs. 1-10.

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<i>S6</i>	CK	Leong, Hoyee et al., "Cytostatic Effects of 3,3'-Diindolylmethane In Human Endometrial Cancer Cells Result from an Estrogen Receptor-Mediated Increase in Transforming Growth Factor- α Expression," <i>Carcinogenesis</i> , Vol. 22, No. 11, 2001, pgs. 1809-1817.
<i>11</i>	CL	Liu, Dan et al., "TGF- α Can Act as Morphogen and/or Mitogen in a Colon-Cancer Cell Line," <i>Int. J. Cancer</i> , Vol. 56, 1994, pgs. 603-608.
<i>11</i>	CM	Liu, Mark C. et al., "Allergy, Rhinitis, other Respiratory Diseases: Effects of Prednisone On the Cellular Responses and Release of Cytokines and Mediators After Segmental Allergen Challenge of Asthmatic Subjects," <i>Journal of Allergy and Clinical Immunology</i> , Vol. 108, No. 1, July 2001, 16 pages.
<i>11</i>	CN	Liu, Ming et al., "Immunohistochemical Study of Transforming Growth Factor-Alpha in Human Lung Cancers," <i>Tumor Biol.</i> , Vol. 13, 1992, pgs. 294-298.
<i>11</i>	CO	Lord, Bl. Et al., "Kinetics of Neutrophil Production in Normal and Neutropenic Animals During the Response to Filgrastim (r-metHu G-CSF) Filgrastim SD/01 (PEG-r-metHu G-CSF)," <i>Clin. Cancer Res.</i> , Vol. 7 July 2001, pgs. 2085-2090.
<i>11</i>	CP	Marquardt and Todaro, "Purification and Primary Structure of a Polypeptide with Multiplication-Stimulating Activity from Rat Liver Cell Cultures," <i>The Journal of Biological Chemistry</i> , Vol. 256, No. 13, July 10, 1981, pgs. 6859-6865.
<i>11</i>	CQ	Marquardt, Hans et al., "Transforming Growth Factors Produced By Retrovirus-Transformed Rodent Fibroblasts and Human Melanoma Cells: Amino Acid Sequence Homology with Epidermal Growth Factor," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 80, August 1983, pgs. 4684-4688.
<i>11</i>	CR	Miettinen, Paivi J., "Transforming Growth Factor- α and Epidermal Growth Factor Expression in Human Fetal Gastrointestinal Tract," <i>Pediatric Research</i> , Vol. 33, No. 5, 1993, pgs. 481-486.
<i>11</i>	CS	Mogi, Makio et al., "Interleuken-1 β , Interleukin-6, Epidermal Growth Factor and Transforming Growth Factor- α are Elevated in the Brain from Parkinsonian Patients," <i>Neuroscience Letters</i> , Vol. 180, 1994, pgs. 147-150.

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<i>Stephen Buckley</i>	<i>5/17/04</i>

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1647

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JAN 22 2001

✓	CT	Nestor, Jr., John J. et al., "A Synthetic Fragment of Rat Transforming Growth Factor α with receptor Binding and Antigenic Properties," <i>Biochemical and Biophysical Research Communications</i> , Vol. 129, No. 1, May 31, 1985, pgs. 226-232.
✓	CU	Ozanne, Brad et al., "Kirsten Murine Sarcoma Virus transformed Cell Lines and a Spontaneously Transformed rat Cell-Line Produce Transforming Factors," <i>Journal of Cellular Physiology</i> , Vol. 105, 1980, pgs. 163-180.
✓	CV	Reid, S. et al., "Radial Migration of Subependymal Cells in the Adult Rodent Forebrain," <i>Society for Neuroscience</i> , Vol. 22, 1996, pg. 1956 (Abstract).
✓	CW	Rimaniol, Anne-Cecile et al., "Biphasic Transforming Growth Factor- β Production Flanking the Pro-Inflammatory Cytokine Response in Cerebral Trauma," <i>NeuroReport</i> , Vol. 7, 1995, pgs. 133-136.
✓	CX	Romano, Marco et al., "Transforming Growth Factor α Protection Against Drug-Induced Injury to the Rat Gastric Mucosa In Vivo," <i>J. Clin. Invest.</i> , Vol. 90, 1992, pgs. 2409-2421.
✓	CY	Rudinger, J., "Characteristics of the Amino Acids as Componenets of a Peptide Hormone Sequence," <i>Biological Council: Peptide Hormones</i> , June 1976, pgs. 1-7.
✓	CZ	Sagar, S.M. et al., "Rapid Communication: Epidermal Growth Factor and Transforming Growth Factor α Induce c-fos Gene Expression in Retinal Muller Cells In Vivo," <i>Journal of Neuroscience Research</i> , Vol. 29, 1991, pgs. 549-559.
✓	DA	Sasada, Reiko et al., "Cloning and Expression of cDNA Encoding Human Betacellulin, A New Member of the EGF Family," <i>Biochemical and Biophysical Research Communications</i> , Vol. 190, No. 3, 1993, pgs. 1173-1179.
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✓	DC	Schultz and Twardzik, "Assessment of Biological Activity of Synthetic Fragments of transforming Growth Factor α ," <i>Methods In Enzymology</i> , Vol. 198, 1991, pgs. 200-213.
✓	DD	Shing, Y. et al., "Betacellulin: A Mitogen from Pancreatic β Cell Tumors," <i>Science</i> , Vol. 259, March 12, 1993, pgs. 1604-1607.

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Stephen Lader

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S6	DE	Skolnick and Fetrow, "From Genes to protein Structure and Function: Novel Applications of Computational Approaches in the Genomic Era," <i>TIBTECH</i> , Vol. 18, January 2000, pgs. 34-38.
11	DF	Song, Si young et al., "Expansion of Pdx1-Expressing Pancreatic Epithelium and Islet Neogenesis in Transgenic Mice Overexpressing Transforming Growth Factor α ," <i>Gastroenterology</i> , Vol. 117, 1999, pgs. 1416-1426.
11	DG	Sottilli, Mauro et al., "Up-Regulation of Transforming Growth Factor α Binding Sites in Experimental Rabbit Colitis," <i>Gastroenterology</i> , Vol. 109, 1995, pgs. 24-31.
11	DH	Sporn and Todaro, "Autocrine Secretion and Malignant Transformation of Cells," <i>The New England Journal of Medicine</i> , Vol. 303, No. 15, October 9, 1980, pgs. 878-880.
11	DI	Subauste and Proud, "Effects of Tumor Necrosis Factor- α , Epidermal Growth Factor and Transforming Growth Factor- α on Interleukin-8 Production By, and Human Rhinovirus Replication in, Bronchial Epithelial Cells," <i>International Immunopharmacology</i> , Vol. 1, 2001, pgs. 1229-1234.
11	DJ	Todaro, George J. et al., "Transforming Growth Factors (TGFs): Properties and Possible Mechanisms of Action," <i>Journal of Supramolecular Structure and Cellular Biochemistry</i> , Vol. 15, 1981, pgs. 287-301.
11	DK	Twardzik, Daniel R. et al., "Similar Transforming Growth Factors (TGFs) Produced by Cells Transformed by Different Isolates of Feline Sarcoma Virus," <i>Virology</i> , Vol. 124, 1983, pgs. 201-207.
11	DL	Weickert and Blum, "Striatal TGF- α : Postnatal Developmental Expression and Evidence for a Role in the Proliferation of Subependymal Cells," <i>Developmental Brain Research</i> , Vol. 86, 1995, pgs. 203-216.
11	DM	Yamamoto, Koji et al., "Recombinant Human Betacellulin Promotes the Neogenesis of β -Cells and Ameliorates Glucose Intolerance in Mice With Diabetes Induced by Selective Alloxan Perfusion," <i>Diabetes</i> , Vol. 49, December 2000, pgs. 2021-2027.
11	DN	Yang, Xiao-Dong et al., "Development of ABX-EGF, A Fully Human Anti-EGF Receptor Monoclonal Antibody, for Cancer Therapy," <i>Critical Reviews in Oncology/Hematology</i> , Vol. 38, 2001, pgs. 17-23.

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Zhang, Maobin et al., "Transforming Growth Factor α and a PC 12-Derived Growth Factor Induce Neurites in PC12 Cells and Enhance the Survival of Embryonic Brain Neurons," *Cell Regulation*, Vol. 1, June 1990, pgs. 511-521.

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